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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,072	12/30/1999	ALAIN CADIEUX	032931-0218	3157

7590 10/21/2002

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/21/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/475,072

Applicant(s)

Cadieux

Examiner

Patrick J. Nolan

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 26, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2, 4-8, 18-21, and 27-36 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4-8, 18-21, 27, 28, and 31-34 is/are rejected.
- 7) ☒ Claim(s) 29, 30, 35, and 36 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 2, 4-8, 18-21, 27-36 are pending and under consideration.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-19-00 has been entered.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2, 4-8, 18-21, 27-28 and 31-34 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,635,478 as evidenced by the Merck Manual (see pages 556-557) for the same reasons set forth in Paper Nos. 5, 7 and 16.

It is noted that U.S. Patent application No. 08/837,114 resulting in U.S. Patent 5,858,978 is a continuation of U.S. Patent application 08/125,275 which resulted in U.S. Patent 5,635,478. The specification's in both are identical. Lastly, claims 28 and 34 have been included in the rejection because the difference between human alpha and beta CGRP is one amino acid as taught by Applicant's specification, the '478 patent does not teach these two forms, however it is customary in science to name the first isolated form of a protein in the alpha form and since Applicant did not provide the office with sequence listing so a comparison between the prior art CGRP and the alpha form could be made, the prior art and the claimed are substantially similar, if not identical and the burden shifts to Applicant to demonstrate any unobvious differences (see MPEP 2112).

Applicant's arguments set forth in Paper No. 22 have been fully considered but are not found persuasive.

Applicant argues that since the '478 patent does not sufficiently limit or well delineate the class of disorders, routes of administration, and pharmaceutical compositions the claimed invention is not anticipated by the prior art reference and that one of ordinary skill in the art could not be able to at once envisage the specific combinations CGRP and asthma.

However, MPEP 2131.02 specifically states

A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES ARE NAMED A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and everyone of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication.").

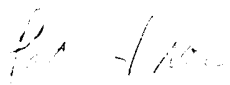
It is the Examiner's position that the use of CGRP to treat asthma is specifically named.

5. It is noted that claims 29-30 and 35-36 are objected to as being dependent upon rejected claims.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 9:30 am to 4:30 pm.
7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

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Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

10-21-02